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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,000	11/25/2003	Peter L. Collins	2303-18-14	6530

7590 09/24/2007  
GRAYBEAL JACKSON HALEY LLP  
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

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09/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/722,000	COLLINS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14-20 and 22-65 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5-11, 15-17, 25-27, 29-33, 37-45 and 49-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 14, 18-20, 22-24, 28, 34-36 and 46-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-11, 14-20, and 22-65 are pending in the application.
2. In the prior action, mailed on January 19, 2007, claims 1-65 were pending, with claims 1-4, 12-14, 18-24, 28, 34-36, and 46-48 under consideration and rejected; and claims 5-11, 15-17, 25-27, 29-33, 37-45, and 49-55 withdrawn from consideration.
3. In the Response of July 18, 2007, the Applicant amended claims 1-3, 14, 15, 18, 20, 52-54, 64, and 65; and cancelled claims 12, 13, and 21. Amended claim 3 now reads on a non-elected embodiment of the claimed invention. This claim is therefore withdrawn from consideration.
4. Claims 1, 2, 4, 14, 18-20, 22-24, 28, 34-36, and 46-48 are under consideration.

#### ***Priority***

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The application has been amended to contain proper reference to the priority applications.

#### ***Claim Rejections - 35 USC § 112***

6. **(Prior Rejection- Withdrawn)** Claims 1-4, 12-14, 18-24, 28, 34-36, and 46-48 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

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invention. The claims were rejected as lacking adequate enabling support for the claimed viruses comprising any RNA polymerase elongation protein. In view of the amendment requiring the presence of the M2-1 RNA polymerase protein, the rejection is withdrawn.

7. **(Prior Rejection- Withdrawn)** Claims 1-4, 12-14, 18-24, 28, 34-36, and 46-48 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated infectious chimeric RSV wherein the virus comprises the M2 (ORF1) RNA polymerase elongation factor, does not reasonably provide enablement for viruses containing any RNA polymerase elongation factor. In view of the amendment requiring the presence of the M2-1 RNA polymerase protein, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **(Prior Rejection- Withdrawn)** Claims 1, 2, 4, 12, 18, 21, 22-24, 35, 36, and 46-48 were rejected under 35 U.S.C. 103(a) as being obvious over Clarke et al. (U.S. 5,840,520) in view of the teachings of Collins et al. (PNAS 92: 11563-67). In view of the amendments to the claims, the rejection is withdrawn.

10. **(Prior Rejection- Maintained)** Claims 1, 2, 4, 12-14, 18, 19, 21-24, 35, 36, and 46-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (U.S. 5,840,520) and

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Collins (PNAS 92: 11563-67), and further in view of Murphy et al. (U.S. 5,922,326). The Applicant traverses the rejection on the basis that the cited references do not teach the specific nucleotide sequences of the mutant viruses, and that knowledge of these changes is critical to the claimed invention. The rejection is withdrawn from amended claim 2, and cancelled claims 12 and 21.

Claim 1 of the present application reads on any chimeric RSV comprising the N, P, M2-1, and L proteins; and a chimeric genome comprising and a partial or complete RSV genome combined with a heterologous segment from another RSV, wherein the chimeric genome includes an attenuating mutation from those identified in the claim. Thus, the claim would read on a chimeric RSV as described wherein the chimeric RSV is a modified RSV 248 comprising a heterologous RSV gene. Such a chimeric virus is suggested by the teachings of Clarke, Collin, and Murphy. In particular, it is noted that Clarke teaches the insertion of additional sequences into RSV genomes, and that Murphy teaches attenuated viruses identified as useful for the induction of anti-RSV immune responses. It would therefore have been obvious to those of ordinary skill in the art to insert the heterologous genes of Clarke into the attenuated viruses of Murphy.

The Applicant asserts that knowledge of the nucleotide sequence of the mutant viruses, and in particular, the specific nucleotide changes resulting in the attenuated phenotypes, would have been requires to combine these teachings. This argument is not found persuasive because knowledge of the specific nucleotide changes that result in the attenuated phenotype would not be required where a heterologous sequence is being inserted into the already attenuated virus. Based on the teachings of Murphy (teaching the screening the effects of further attenuating

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conditions on already attenuated phenotypes) and of Collins (teaching the need for fine-tuning vaccine viruses) it would have been obvious to those of ordinary skill in the art to incorporate modifications disclosed in Clarke into the viruses of Murphy, and to screen the resulting viruses for improved vaccine qualities. The rejection is therefore maintained.

11. **(Prior Rejection- Restated as Necessitated by Amendment and Maintained)** Claims 1-4, 12, 18, 21-24, 34, 35, 36, and 46-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke and Collins as applied to claims 1, 2, 12, 18, 21, 22-24, 35, and 46-48 above, and further in view of Wertz et al. (U.S. 5,789,229). This rejection is withdrawn from amended claim 3 (now withdrawn) and from cancelled claims 12, 13, and 21. In view of the Amendment of claim 1, the rejection is restated as a rejection of claims 1, 2, 4, 14, 18, 19, 22-24, 34-36, and 46-48 over the teachings of Clarke, Collins, Murphy, and Wertz.

The Applicant traverses the rejection on the basis of the incorporation of the limitations of claim 13 (relating to the inclusion of the attenuating mutation from RSV 248) into claim 1. As the rejection has been restated to include the teachings of Murphy, which accounts for the limitations of previous claim 13, the rejection is maintained.

#### ***Double Patenting***

12. **(New Warning)** Applicant is advised that should claim 3 be found allowable, claim 34 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same

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thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. **(Prior Rejection- Maintained)** Claims 1, 4, 12, 14, 18, 19, 20-24, 28, 35, and 46-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 12, 14, 18, 20-25, 28, and 31-34 of U.S. Patent No. 6,689,367. It is noted that claim 13 was inadvertently left out of the prior rejection. Nonetheless, the elected limitation of claim 14 corresponds to the same substitution. Further, claim 13 of the patent specifically addresses the limitations now incorporated into present claim 1. Thus, the incorporation of the limitations of claim 13 into claim 1, which limitation was previously addressed in alternative language via claim 14, is not considered to raise new issues. The rejection is withdrawn from cancelled claims 12 and 21.

Applicant's arguments regarding the presence of a restriction requirement in the application from which that patent was issued is noted. The argument is not found persuasive in view of (a) the fact that the patented claims specifically read on species of the presently claimed inventions and the present claims read on the patented claims (i.e. claims presented in these applications are not consonant with the restriction requirement- see e.g., MPEP 804.01); and (b) that the restriction requirement in that application was withdrawn in the Notice of Allowance mailed in that application on August 26, 2003. The rejection is therefore maintained.

15. **(Prior Rejection- Withdrawn)** Claims 1-4, 12, 14, 18, 19, 20-24, 28, 35, and 46-48 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-8, 23-28, 39, 50, 51, 59-61 of U.S. Patent No. 6,713,066 in view of the teachings of Clarke (*supra*). In view of the submission of a terminal disclaimer with respect to this patent, the rejection is withdrawn.

16. **(Prior Rejection- Withdrawn)** Claims 1-4, 12-14, 18, 19, 21-24, 28, 34-36, and 46-48 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 63, 77, 78, 87-90, 92, 101, 102, 109-111 of copending Application No. 10/934,003 in view of the teachings of Collins (*supra*). In view of the submission of a terminal disclaimer with respect to this application, the rejection is withdrawn.

17. **(Prior Rejection- Withdrawn)** Claims 1-4, 12-14, 18-24, 34-36, 46-48 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 10, 11, 30-37, 46, 47, 57-59, 90, and 91 of copending Application No. 11/033996. In view of the abandonment of this application, the rejection is withdrawn.



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18. **(Prior Rejection- Withdrawn)** Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/097,946. In view of the submission of a terminal disclaimer with respect to this application, the rejection is withdrawn.

19. **(Prior Rejection- Withdrawn)** Claims 1-4, 12-14, 18-24, 34-36, and 46-48 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 11, 30-37, 46, 47, 57-59 of copending Application No. 11/203620. In view of the submission of a terminal disclaimer with respect to this application, the rejection is withdrawn.

### *Conclusion*

20. No claims are allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/

Patent Examiner, AU 1648